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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Spinal implants - Pre-clinical mechanical assessment and
particular requirements - Parts 2: Spinal intervertebral body
fusion devices**

脊柱植入器械 临床前力学性能评价和特殊要求 第2部分：椎间融合器
(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is modified to adopt ISO 23089-2:2021 "Preclinical mechanical properties evaluation and special requirements for surgical implants Part 2: Vertebral Inter-fusion device.

The technical differences between this document and ISO 23089-2:2021 and their reasons are as follows.

--- Regarding normative references, this document has been adjusted with technical differences to adapt to my country's technical conditions.

The situation is reflected in Chapter 2 "Normative Reference Documents", and the specific adjustments are as follows.

- Replaced ISO 14630 with YY/T 0640 which is equivalent to the international standard;
- YY/T 0959 replaced ASTM F2077;
- YY/T 0960 replaced ASTM F2267.

The following editorial changes were made to this document.

--- Changed the name of the standard to replace "surgical implants" with "spinal implants" to clarify the specific application areas of the standard;

--- Added "This document is applicable to the evaluation of spinal intervertebral fusion devices used in spinal fusion surgery" to improve the scope of application of this document Limited (see Chapter 1);

- The abbreviation for interbody fusion devices (IBFDs) (see Chapter 3) has been deleted to avoid confusion;
- Changed the explanation of the data source in Table 1 as a note (see 4.3);
- Deleted "or when the local regulatory authority does not accept the first two options" in 4.3c).

Introduction

Spinal interbody fusion cages are used to treat various spinal lesions. After the intervertebral disc is removed, the interbody fusion cage is implanted between adjacent vertebrae to maintain Increase intervertebral height and provide mechanical stability to the spine during spinal fusion.

The purpose of this document is to establish the minimum requirements for performance testing necessary during the development of interbody fusion devices.

Users are concerned about interbody fusion devices with design features that require additional testing (evaluation).

It may be necessary to conduct additional evaluation of aspects of cage technology not fully covered in this document, such as, but not limited to. coating properties;

energy, impact testing, breakout testing and additive manufacturing process validation.

Preclinical evaluation of mechanical properties of spinal implants and Particular requirements - Part 2: Interbody fusion cages

1 Scope

This document specifies specific requirements for the evaluation of the mechanical properties of spinal interbody fusion cages used in spinal fusion procedures.

This document applies to the evaluation of spinal interbody fusion devices used in spinal fusion procedures.

This document focuses mainly on mechanical requirements and does not include all evaluation contents of different types of spinal interbody fusion devices.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

YY/T 0640 General requirements for passive surgical implants (YY/T 0640-2016, ISO 14630:2012, IDT) YY/T 0959 Test method for mechanical properties of spinal implants and intervertebral fusion devices YY/T 0960 Test method for static axial compression sinkage of spinal implant intervertebral fusion cage

3 Terms and definitions

The terms and definitions defined in YY/T 0640 apply to this document.

The URLs of ISO and IEC databases for standardization are as follows.

4.1 General

The intervertebral fusion cage functions as a load-bearing implant and bears corresponding mechanical loads according to its implantation position in the spine.

The mechanical evaluation of the clutch should consider the performance of the device under the following loading modes.

---Axial compression. Axial compression load is the main mechanical load that the intervertebral fusion cage bears in the body.

---Compression-shear. The shear load on the intervertebral fusion cage is the shear load on the spine caused by the daily activities of the spine due to spinal curvature (e.g., lumbar and the cervical spine is lordotically deformed and is caused by the compressive load applied by the cervical spine).

---Torsion. Torque is generated by the spine during daily activities (torsion performance is most common for devices intended to be implanted in the cervical spine).

See the evaluation content).

If the loading mode of this clause is deemed unnecessary for the evaluation of interbody fusion cages, the user of this document may choose If it chooses not to carry out the evaluation, it should provide a valid reason for that decision.

4.2 Test methods

Intervertebral fusion devices should be evaluated using the following test methods. If the following test methods cannot be used, sufficient reasons should be provided.

---Axial compression test. The static and fatigue properties (e.g., yield strength, stiffness and fatigue load) are evaluated in accordance with YY/T 0959.